UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/368,010	08/03/99	KASPER K	BEH-7443

HM12/1101

DADE BEHRING INC.
1717 DEERFIELD ROAD, #778
ATTN: LOIS K. RUSZALA
DEERFIELD IL 60015-0778

EXAMINER	
CEPERLEY, M	
ART UNIT	**PAPER NUMBER**
1641	4

DATE MAILED: 11/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/368,010	KASPER et al
Examiner	**Group Art Unit**
Mary E. Ceperley	1641

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____*one*_____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-82* _____ is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-82* _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 4, 16-18, 40, 41, and 56, drawn to a monoclonal antibody to tacrolimus designated 1H6, a hybridoma which produces this antibody, a detectably labeled monoclonal antibody, and an immunoassay and test kit which use this antibody, classified in class 530, subclasses 388.4, 391.3; 435/188; 436/544, 545, 546, and 815.

II. Claims 2, 3, 5, 6-9, 19-27, 42-47, and 57-59, drawn to a different monoclonal antibody to tacrolimus, a hybridoma which produces this antibody, a humanized form of this antibody, a single-chain recombinant antibody derivative of this monoclonal antibody, detectably labeled monoclonal antibodies, and immunoassays and test kits which use this antibody.

III. Claims 10, 28-30, 48, 49, and 60, drawn to a monoclonal antibody to tacrolimus produced by fusion of cells from a mammal immunized with tacrolimus derivatized with a carboxymethyl oxime moiety at a carbon atom in the non-binding domain of tacrolimus, a detectably labeled monoclonal antibody, and an immunoassay and test kit which use this antibody.

IV. Claims 11, 12, 31-33, 50, 51, and 61, drawn to a monoclonal antibody to tacrolimus produced by fusion of cells from a mammal immunized with tacrolimus derivatized with a carboxymethyl oxime moiety at carbon atom 22, a detectably

labeled monoclonal antibody, and an immunoassay and test kit which uses this antibody.

V. Claims 13, 34-36, 52, 53, and 62, drawn to an antibody produced by immunization of a mammal with an immunogen prepared by derivatizing tacrolimus with a carboxymethyl oxime moiety at a carbon atom in the non-binding domain, a detectably labeled monoclonal antibody, and an immunoassay and test kit which use this antibody.

VI. Claims 14, 15, 37-39, 54, 55, 63, drawn to an antibody to tacrolimus produced with an immunogen in which the hapten is derivatized with an oxime moiety at carbon atom 22, a detectably labeled monoclonal antibody, and an immunoassay and test kit which uses this antibody.

VII. Claims 64, drawn to a tacrolimus compound that is derivatized with a carboxymethyl oxime moiety at a carbon atom in the non-binding domain of tacrolimus.

VIII. Claims 65, 70, 73-75, drawn to a tacrolimus compound which is derivatized with a carboxymethyl oxime moiety at carbon atom 22, a method of preparing it, a biotin derivative thereof and a method for its preparation.

IX. Claim 66, 67 drawn to an immunogen in which the hapten is derivatized with a carboxymethyl oxime moiety at a carbon atom in the non-binding domain of tacrolimus, class 530, subclass 403.

X. Claim 68, 69, 71, 72, drawn to an immunogen in which the hapten is derivatized with a carboxymethyl oxime moiety at carbon atom 22 and a method of preparing it.

XI. Claim 76, drawn to a bromoacetyl derivative of tacrolimus that is derivatized at a carbon atom in the non-binding domain of tacrolimus,

XII. Claim 77, 82, drawn to a bromoacetyl derivative of tacrolimus that is derivatized at carbon atom 22 and a method for its preparation, class 540.

XIII. Claim 78, 79, drawn to a derivative of claim 76 conjugated to a protein.

XIV. Claim 80, 81, drawn to a derivative of claim 77 conjugated to a protein.

2. The inventions are distinct, each from the other because of the following reasons:

a. Each of Inventions I, II, III, IV, V, and VI is unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the monoclonal antibodies of the different inventions have different specificities/cross-reactivities.

b. The tacrolimus derivatives of Inventions VII-XIV are unrelated for the reason that each invention is drawn to compounds which have different structures including different chemical functionalities and the compounds have different methods of use. A reference which would

anticipate a derivative of one invention would not necessarily render obvious a derivative of another invention.

c. Inventions a) VII and IX, b) VIII and X, c) XI and XIII and d) XII and XIV are each related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as a component of a label-hapten tracer conjugate and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter requiring different fields of search and different patentability considerations, restriction for examination purposes as indicated is proper.

4. Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. (Molly) Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

mec
c:\docs\actions\368010.res
October 31, 2000
Disk: 10/00

Mary E. Ceperley
Primary Examiner
Art Unit 1641